

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

SAFETY GUIDE

Radiation Protection in Diagnostic and Interventional Radiology

RADIATION PROTECTION SERIES No. 14.1

Radiation Protection Series

The **Radiation Protection Series** is published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to promote practices which protect human health and the environment from the possible harmful effects of radiation. ARPANSA is assisted in this task by its Radiation Health and Safety Advisory Council, which reviews the publication program for the **Series** and endorses documents for publication, and by its Radiation Health Committee, which oversees the preparation of draft documents and recommends publication.

There are four categories of publication in the *Series*:

Radiation Protection Standards set fundamental requirements for safety. They are regulatory in style and may be referenced by regulatory instruments in State, Territory or Commonwealth jurisdictions. They may contain key procedural requirements regarded as essential for best international practice in radiation protection, and fundamental quantitative requirements, such as exposure limits.

Codes of Practice are also regulatory in style and may be referenced by regulations or conditions of licence. They contain practice-specific requirements that must be satisfied to ensure an acceptable level of safety in dealings involving exposure to radiation. Requirements are expressed in 'must' statements.

Recommendations provide guidance on fundamental principles for radiation protection. They are written in an explanatory and non-regulatory style and describe the basic concepts and objectives of best international practice. Where there are related **Radiation Protection Standards** and **Codes of Practice**, they are based on the fundamental principles in the **Recommendations**.

Safety Guides provide practice-specific guidance on achieving the requirements set out in **Radiation Protection Standards** and **Codes of Practice**. They are non-regulatory in style, but may recommend good practices. Guidance is expressed in 'should' statements, indicating that the measures recommended, or equivalent alternatives, are normally necessary in order to comply with the requirements of the **Radiation Protection Standards** and **Codes of Practice**.

In many cases, for practical convenience, regulatory and guidance documents which are related to each other may be published together. A **Code of Practice** and a corresponding **Safety Guide** may be published within a single set of covers.

All publications in the *Radiation Protection Series* are informed by public comment during drafting, and Radiation Protection Standards and Codes of Practice, which may serve a regulatory function, are subject to a process of regulatory review. Further information on these consultation processes may be obtained by contacting ARPANSA.



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This publication was approved by the Radiation Health Committee on 16 July 2008, and endorsed for publication by the Radiation Health & Safety Advisory Council on 8 August 2008

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ISBN 978-0-9803236-8-9 ISSN 1445-9760

The mission of ARPANSA is to provide the scientific expertise and infrastructure necessary to support the objective of the ARPANS Act - to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.

Published by the Chief Executive Officer of ARPANSA in August 2008

Foreword

The Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology is one of three guides that support the application of the Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (the Code).

The use of X-ray equipment, particularly CT, in medicine is increasing throughout Australia. As *the Code* makes clear, the fundamentals of justification and optimisation must apply when performing diagnostic and interventional radiology procedures. Exposure to radiation during a medical procedure needs to be justified by weighing up the benefits against the detriments that may be caused. This includes considering the benefits and risks of alternate methods that do not involve any exposure to radiation. In the case of optimisation, practitioners need to ensure that the minimum amount of radiation is used to give the intended diagnostic objective. This *Safety Guide* encourages the use of Diagnostic Reference Levels (DRLs) as a tool to support optimisation of protection to the patient. The protection of occupationally exposed staff and the general public are also an important aspect of the optimal use of ionizing radiation in medicine. Special concern in relation to radiation protection is afforded to children, and pregnant or potentially pregnant females.

The Code establishes the regulatory requirements for the use of ionizing radiation in medicine. This *Safety Guide* was written to give practitioners in diagnostic and interventional radiology a best practice approach to their day-to-day clinical work. It should also assist in providing practical means to meet the mandatory requirements of *the Code*. One such area is the preparation, implementation and review of a Radiation Management Plan.

A draft of the *Safety Guide* was released for industry consultation between 18 May 2007 – 2 July 2007 and was subsequently revised by the working group. A public consultation period from 24 August 2007 to 26 October 2007 followed. A one-day *National Conference on Radiation Protection in Medicine* was held on 3 October 2007, during the public consultation period, to provide the stakeholders a forum to discuss the Code and the three Safety Guides. The *Safety Guide* was again revised by the working group to take into account the comments made in the submissions. The Radiation Health Committee approved the final *Safety Guide* at their meeting of 16-17 July 2008 and the Radiation Health and Safety Advisory Council advised me to adopt the Safety Guide at its meeting on 8 August 2008.

I expect that the Radiation Health Committee will review the *Safety Guide* in two years, and update it if necessary, to ensure that it provides the highest standards of protection for the medical use of ionizing radiation.

John Loy PSM CEO of ARPANSA

27 August 2008

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1. Introduction

1.1 CITATION

This Safety Guide may be cited as the *Safety Guide for Radiation Protection Diagnostic and Interventional Radiology* (2008).

1.2 BACKGROUND

This Safety Guide has been prepared as a supplement to the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation* (2008) (ARPANSA 2008) (hereafter called 'the Code'). It provides advice and guidance on good radiation **practice** and on meeting the requirements of the Code.

1.3 PURPOSE

The guidance offered in this Safety Guide is not mandatory. The measures herein should however be implemented in the interests of reducing radiation **exposure** and risks. It provides information to help obtain satisfactory clinical outcomes with minimum exposure to radiation of the patient, the clinician and other persons involved with the examination. It includes information on:

- allocation of responsibilities;
- clinical assessment of the indications for radiography;
- provision of appropriate X-ray and ancillary equipment; and
- adoption of procedures to minimise exposure to radiation.

1.4 SCOPE

This Safety Guide applies to the following exposures:

- the exposure of patients as part of their medical diagnosis;
- the exposure of individuals as part of health screening programs;
- the exposure of individuals participating in research programs¹;
- the exposure of individuals as part of medico-legal procedures;
- the **occupational exposure** of individuals arising from the use of medical radiation equipment;
- the exposure of health professionals other than those with training in the medical applications of **ionizing radiation**;
- the exposure of **carers**, being those individuals who voluntarily assist patients undergoing relevant procedures; and
- the exposure of members of the public arising from the use of medical radiation equipment.

¹ See also the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)*, ARPANSA (ARPANSA 2005)

This Safety Guide applies to individuals, practices or institutions where Radiation diagnostic or interventional radiological examinations are undertaken but **Protection** does not apply to:

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- dental radiology; •
- veterinary radiology; •
- radiotherapy (including treatment planning with dedicated equipment); •
- the use of various molecular imaging and nuclear medicine computed • tomography (CT) systems;
- combined CT/PET and CT/SPECT equipment where the CT scanning • component is not utilised for diagnostic purposes; or
- the individuals involved with these practices.

Separate Codes and Safety Guides cover these practices and their practitioners (ARPANSA 2005a, ARPANSA 2008a, ARPANSA 200x, ARPANSA 200y).

1.5 **STRUCTURE**

This Safety Guide sets out information that should assist in achieving the levels of protection specified in the Code. While it does not form part of the material directly adopted into the regulatory frameworks of the State, Territory or Commonwealth Authorities, it does set out best practice in diagnostic and interventional radiology and therefore the use of this Safety Guide is recommended for establishing appropriate radiation The Safety Guide does not restrict users from protection procedures. developing their own institutional procedures that provide an equivalent level of safety to meet the requirements of the Code.

The meaning of terms defined in the Glossary to this Safety Guide are the same as the meaning defined in the Glossary to the Code.

Material in the Annexes provides clarification and guidance on issues discussed in the Safety Guide with Annex C, in particular, outlining the health effects arising from exposure to ionizing radiation.

2. Justification

All diagnostic exposures to ionizing radiation are subject to the principles of **justification** and **optimisation**. For **doses** received by a patient undergoing medical diagnosis or treatment, there are two levels of justification.

- 1. Each new and existing procedure involving exposure to radiation needs to be justified in principle (clause 2.1 of the Code). As matters of effective medical practice will be central to this judgement, the continuing involvement of medical professional societies should be ensured (IAEA 2002).
- 2. The **Radiation Medical Practitioner** responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation will need to justify each procedure on a further, case-by-case justification (ICRP 2004) (clause 3.1.3 of the Code). In diagnostic radiology, this person will usually be a radiologist, but might also be, for example, a cardiologist or general practitioner.

The decision to perform a radiographic or interventional examination rests upon a professional judgement of the total health benefit to the patient, as opposed to any biological effects that the ionizing radiation might cause. The benefit will be the potential diagnostic information or therapeutic effect of an interventional procedure resulting from the **medical exposure**, including the direct health benefits to the individual as well as the benefits to society. The **detriment** is the potential deleterious effects of exposure to ionizing radiation although the Radiation Medical Practitioner should also consider other health detriments when deciding on a particular examination. For example, a particular procedure might involve a higher radiation dose to a patient but the non-radiation related risk from performing that procedure could be lower than an alternate procedure with lower radiation dose.

Doses from diagnostic imaging have the potential to cause detriments of a **stochastic** nature, these being:

- cancer in the exposed individual; or
- genetic mutations, which can also pass on to future offspring.

The probability of these stochastic detriments occurring is determined by:

- the age of the patient;
- the anatomical region being exposed; and
- the size of the dose.

There is no threshold below which stochastic detriments cannot occur.

For interventional radiology procedures however, an additional concern relates to possible **deterministic effects** such as skin damage (ICRP 2000a). The severity of deterministic effects increases with increasing dose, usually with a threshold below which they do not occur.

The justification process should also take into account the efficacy, benefits and risks of using alternative imaging modalities involving no, or less, exposure to ionizing radiation e.g. ultrasound, magnetic resonance imaging and endoscopy (IAEA 2002, ICRP 2004). Also influencing this choice will be practitioner preference, expertise, and the availability of the differing imaging modalities.

Radiology is a most valuable aid to diagnosis when employed in accordance with the general health needs of the individual patient, but its use needs to be tailored to the needs of that patient. Special cases that warrant further justification include:

- The medical exposure of the pregnant or potentially pregnant patient is of particular concern, as there is some evidence to suggest that the embryo or fetus is more radiosensitive than is a mature adult (Delongchamp *et al* 1997, Doll and Wakeford 1997).
- Likewise, radiological examinations of children under the age of 18 years require a higher level of justification since they have a longer life expectancy in which the manifestation of possible harmful effects of radiation may occur. Additionally, children may be more susceptible to radiation-induced cancers (ICRP 1991a, ICRP 1991b, Delongchamp *et al* 1997).
- When consideration is being given to litigation, repeat radiographic examinations for medico-legal purposes should not be undertaken if clinical indications no longer exist unless the referring specialist considers such a procedure is essential for the adequate assessment of long-term disability.
- Research that exposes humans to ionizing radiation should conform to the requirements published by the National Health and Medical Research Council (NHMRC) (NHMRC 2007), ARPANSA (ARPANSA 2005) and the International Commission on Radiological Protection (ICRP) (ICRP 1991b).
- Mass screening (non-referral) of targeted population groups is rarely justified. Such screening can only be justified if there is demonstrable evidence that the benefit to society is sufficient to compensate for the economic and social costs and any potential health detriment associated with the examinations. The detriment needs to include consideration of any morbidity, including anxiety, and the radiation risks associated with the examination. Breast cancer screening provides an example of one screening program that may be justified based on studies that have demonstrated net benefit to society (Tabar *et al* 2003). However, there are newly evolving screening practices for which there has been no demonstration of a net benefit at the time of publication e.g. whole body CT scanning. The relevant professional medical bodies do not endorse such practices. In all instances a full disclosure of the potential detriment, including but not limited to the radiation risks, needs to be made to the individual.
- The **referrer** and/or practitioner should not proceed with the intended exposure unless they can demonstrate a sufficient net benefit. Nor should

they perform radiological procedures as an alternative to taking a thorough history and physical examination, or merely to protect the referring clinician from possible legal action.

Within the demands of clinical urgency, a patient who requires medical treatment following trauma should undergo a thorough clinical examination before having a radiological procedure. Unless adequate clinical indications for radiography exist, referring an individual for a radiological procedure for legal purposes is not justified.

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3. Duties and Responsibilities

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3.1 RESPONSIBLE PERSON

The **Responsible Person** is legally responsible for adherence to the Code unless specific obligations of the Radiation Medical Practitioner or the **operator** are stated (Section 3.1 of the Code). Although the Responsible Person may delegate some tasks to others such as a Radiation Safety Officer (RSO), the ultimate responsibility lies with the Responsible Person. Where the Responsible Person decides to appoint an RSO, the RSO will typically have the duties outlined in Annex B of this Safety Guide.

The radiation regulatory authorities in Australia require that all operators of diagnostic and interventional X-ray equipment either hold a current **authorisation** to operate the equipment or be otherwise exempt.

3.1.1 Radiation Management Plan

Clause 3.1.1 of the Code requires that the Responsible Person has a Radiation Management Plan in place for the control of radiation exposure. The RSO or a **qualified expert**, working closely with relevant staff and practitioners, would normally develop the Radiation Management Plan. Both the Radiation Management Plan and its implementation need regular review. The Radiation Management Plan should include written procedures or protocols to address:

- the protection of **employees**, patients and members of the public;
- personnel monitoring requirements;
- shielding and design of installations and an inventory of radiological equipment;
- the correct identification of the patient prior to the study being performed;
- irradiation of pregnant or potentially pregnant women with specific advice about how to minimise the chance of unintentionally irradiating the unborn child (see also section 5);
- paediatric radiology given the acknowledged higher radiosensitivity of children;
- concerns about the risks from ionizing radiation and how to explain them to patients, guardians and carers;
- the protection of individuals (carers), who voluntarily help in the care, support or comfort of patients undergoing diagnostic or interventional radiology examinations. Carers are individuals who are not normally occupationally exposed (e.g., relatives and friends over the age of eighteen who are not pregnant) and nurses and support staff, for example, should only assist if a carer is not available. Further, the Responsible Person should be able to demonstrate that the **effective dose** received by a carer, who voluntarily helps in the care, support or comfort of patients

undergoing diagnostic or interventional radiology examinations, is unlikely to exceed 5 mSv per year (IAEA 1996);

- specific instructions for tailoring procedures to patient size and the clinical need. These should be developed for all radiological procedures and are particularly important for procedures that involve higher patient doses such as Computed Tomography (CT) examinations (ICRP 2000c, ICRP 2001);
- interventional procedures where the risk to the patient may be from both deterministic and **stochastic effects** (ICRP 2000a). Documented working procedures should be implemented for each major subgroup of interventional procedures [e.g. coronary angioplasty, Trans-jugular Intrahepatic Porto Systemic shunt (TIPS) etc.]. Procedures should be in place to audit practices and to ascertain whether any radiation-induced complications occur;
- the irradiation of volunteers as part of research programs;
- radiation incidents (see section 8); and
- regulatory requirements that need to be satisfied.

3.1.2 X-ray equipment

All radiation regulatory authorities in Australia require that X-ray equipment used for diagnostic and interventional radiology meet specific authorisation criteria, which are usually based on relevant Australian/New Zealand standards and those of the International Electrotechnical Commission (IEC).

The Responsible Person should make sure that the safety, calibration and performance of X-ray equipment are checked:

- at the time of commissioning of the unit;
- after any maintenance procedure that may have an effect on the performance of the unit; and
- at intervals recommended by the X-ray equipment manufacturers.

Any dosimetry equipment used to perform such checks needs to have a calibration traceable to an acceptable national or international standard.

The Responsible Person should limit the use of portable or mobile equipment to those circumstances where it is impractical or not medically acceptable to transfer the patient to a fixed radiological installation. Fundamentally, there are two reasons for this.

- Such equipment:
 - is relatively low-powered;
 - offers a very restricted choice of technique factors; and
 - is frequently not equipped with ancillary equipment such as Bucky grids.

Mobile and portable equipment rarely offer the degree of protection to the patient, operator and other employees that is afforded by fixed installations.

Direct viewing fluoroscopy is not acceptable and there is therefore a requirement to use either:

- an **image intensifier** coupled to a television chain; or
- a **flat panel detector** system.

3.1.3 Personal radiation monitoring devices

Clause 3.1.9 of the Code requires that the Responsible Person provide each employee who is likely to receive an annual effective dose of more than 1 mSv, either because of:

- chronic exposure; or
- incidents that are reasonably foreseeable,

with an **approved** personal radiation-monitoring device. Therefore, not all employees who may receive an occupational exposure require personal monitoring.

Wearing periods for personal radiation monitors will vary depending on the likelihood of the individual receiving an accidental or high dose but in any event should never be for longer than three months.

It is appropriate in some circumstances for an individual to wear two personal monitoring devices (e.g. employees regularly involved in interventional radiology). When a single monitoring device is used, that person should wear it:

- on the trunk;
- between the waist and the chest; and
- under any protective garments.

However, if a person wears two devices, that person should wear the:

- first one as described above; and
- second one outside any protective garments at collar level.

For practitioners performing interventional procedures, it may be appropriate to issue extremity monitors to confirm that doses to the fingers are well below the extremity dose limits, for example, a quarter of the deterministic pro rata dose limit for the extremities. Monitors manufactured in the form of a ring are most suitable for this purpose however, other types of monitors might be available.

3.1.4 Dose limitation, the ALARA principle and image quality

While the Code requires that the Responsible Person keep all exposures to occupationally exposed persons and the public below the individual dose limits specified in RPS1 (ARPANSA 2002), it should be noted that ICRP60

(ICRP 1991a) recognises that these dose limits represent the boundary between unacceptable doses and doses that are tolerable. As part of the optimisation process, clause 3.1.4 of the Code requires that the Responsible Person keep individual doses as low as reasonably achievable (ALARA), economic and social factors being taken into account and the use of **dose constraints** is therefore strongly encouraged.

With regard to patient doses, and in the spirit of ALARA, when a patient is transferred to a different institution or practice, the Responsible Person should ensure that all relevant images and reports, or duplicates of the images and reports, relating to that patient are provided to the new practice. This may help to reduce the incidence of repeat examinations and therefore unnecessary patient exposures.

The digital revolution has brought with it a change in the production, reporting and distribution of medical images. In particular, there is wider use of total digital solutions in the form of picture archiving and communications systems (PACS) and teleradiology. These systems, while having many benefits, do have their own potential limitations (ICRP 2004). It is important therefore that the image medium, whether soft copy or film, used for primary diagnosis and reporting does not compromise the diagnostic quality of the image. Original images on film may be digitised for distribution to clinical staff but such images may suffer from a loss of diagnostic integrity in the digitisation and transmission process and should not be used for primary diagnosis and reporting.

3.2 REFERRERS

The referrer of the patient for a diagnostic or interventional procedure should be satisfied that the procedure is justified. In that respect, the referrer may need to discuss the merit of a particular examination with the Radiation Medical Practitioner responsible for the conduct of that examination (ARPANSA 2002, ICRP 1991a).

The referrer should provide accurate patient identity details for the intended patient as incidents of the incorrect patient ID sticker being placed on a written referral have occurred in the past. Where applicable, the request should also alert the Radiation Medical Practitioner to the possibility that a particular female patient is likely to be pregnant.

3.3 OPERATORS

Before any procedure is undertaken, the operator needs to:

- comply with the centre's operating procedures on how to identify the patient correctly (clause 3.3.5 of the Code);
- establish the identity of the patient by:
 - name;
 - gender; and
 - at least one of date of birth, address and any unique patient number;

•

ensure that the correct procedure will be performed (clause 3.3.4 of the Code).

The operator will typically be a radiographer or the Radiation Medical Practitioner. If the operator is concerned about the relevance of the procedure indicated on the request form, he or she should take this issue up with the Radiation Medical Practitioner or the referrer. Radiographers are more than competent to:

- raise and outline concerns regarding examination requests with the referrer; and
- provide advice to referrers on alternate and/or extended imaging examinations.

In keeping with the recommendations of the ICRP (ICRP 2000a), it is good practice for the Responsible Person to have systems in place for routinely auditing the work practices of operators of interventional radiology equipment to ensure that:

- operational protocols are optimised;
- processes that identify patients previously irradiated are properly followed; and
- records of relevant technical information [screening time, **dose-area product** (DAP), **entrance surface dose** (ESD), etc.] are recorded in the patient's record.

Clause 3.3.7 of the Code requires that the operator, as the person who delivers the dose to the patient, take appropriate steps so that the primary X-ray beam does not expose anybody unnecessarily other than the patient. For example, the operator can minimise the dose to a carer who is required to hold a patient during a radiological examination by providing protective aprons to the carer.

Additionally, operators of ionizing radiation apparatus that have the potential to deliver high doses, such as CT scanners or interventional radiology equipment, should:

- be thoroughly familiar with any dose reduction techniques specific to the equipment that he or she will operate; and
- routinely review their work practices to optimise operational protocols.

Section 4 of this Safety Guide covers best practice for an operator, such as dealing with optimisation of protection of the patient.

3.4 THE RADIATION MEDICAL PRACTITIONER

Clause 3.2.1 of the Code (see also IAEA 2002) requires that the Radiation Medical Practitioner responsible for overseeing the radiological exposure make the ultimate decision to perform or reject each individual radiological procedure. The Radiation Medical Practitioner should base that decision on knowledge of the:

- hazard associated with the radiological exposure; and
- clinical information that the referrer supplies.

Accordingly, the Radiation Medical Practitioner may need to liaise closely with the referrer about the merit of performing a particular examination. Any decision to proceed or not should be made after consideration of the timely availability of alternative tests, which involve less or no exposure to ionizing radiation. This is particularly pertinent in cases when the irradiation of pregnant women is being contemplated. The Radiation Medical Practitioner should therefore weigh the implications of delaying a diagnosis in order to use the preferred test method against the potential detriment associated with the increased radiation burden to the patient that would arise from a test involving ionizing radiation.

The Radiation Medical Practitioner has particular responsibility to optimise the conduct of a CT examination by balancing the clinical need against the radiation dose. CT has the capacity to deliver a large radiation dose rapidly to the patient:

- at a level that may cause deterministic and stochastic effects; and
- without limitation by tube heat capacity.

For appropriate supervision of CT scanning procedures, the Radiation Medical Practitioner should:

- assess each CT referral for diagnostic and clinical appropriateness with a view to preventing unnecessary CT examinations;
- communicate directly with the referrer to seek clarification if the referral:
 - is inappropriate;
 - is ambiguous; or
 - would lead to a radiation exposure that does not answer the clinical question being posed;
- where it is clinically appropriate, and in consultation with the referrer:
 - substitute other imaging tests that do not use ionizing radiation;
 - modify the examination; or
 - cancel the examination altogether;
- optimise the radiation dose delivered to the patient through balancing the clinical need against the radiation dose;
- limit the procedure scope (e.g. by restricting areas to be scanned or the number of phases to answer only the clinical question);
- optimise the examination protocol in unclear circumstances by, for example:
 - reducing the dose;
 - changing the area scanned;
 - changing the patient preparation; and/or
 - changing to a non-ionizing imaging modality; and

communicate the decisions about the choice of examination and the outcomes of the imaging workup to the referrer.

The Radiation Medical Practitioner should take all appropriate steps to obtain informed patient consent, consistent with the institution's policies, as a fundamental component of sound medical practice. The ICRP (ICRP 2000a) strongly recommends that the potential risks from the radiation exposure be explained in a meaningful way with respect to deterministic effects for potentially lengthy and/or complex interventional procedures. The Radiation Medical Practitioner should therefore provide the patient with information on the possibility of skin damage, even though these occurrences are rare and only occur due to lengthy procedures. It is also appropriate that the Radiation Medical Practitioner keep data that would allow estimates of skin doses in the patient's medical record. In cases where a patient receives a high skin dose:

- post procedure counselling may be warranted;
- the patient's personal physician should be informed of the possibility of radiation induced deterministic effects; and
- ten to 14 days after exposure, the physician or referrer should follow up any patient who has received an estimated skin dose of approximately 3 gray or above (ICRP 2000a).

3.5 RADIATION SAFETY OFFICER (RSO)

The Responsible Person may delegate radiation protection duties to a RSO. In some Australian jurisdictions, the **relevant regulatory authority** requires that an RSO be appointed as a pre-requisite for the issue of an authorisation.

An RSO will have sufficient professional and/or technical training to oversee and provide advice on radiation safety within the centre. The RSO will generally keep the Responsible Person informed of the radiation safety status of the centre.

The RSO can be an employee or an external consultant. Where a given jurisdiction mandates the appointment of an RSO, such an appointment will be subject to the requirements of the relevant regulatory authority.

The Responsible Person may direct the RSO to develop an institutional radiation safety manual or Radiation Management Plan to cover the use of ionizing apparatus. In developing and implementing the Radiation Management Plan, the RSO should liaise with the relevant medical imaging staff. The Radiation Management Plan would normally assign the duties listed in Annex B to the RSO.

In a tertiary-level hospital, the RSO's duties will cover all uses of radiation within the institution including:

- nuclear medicine;
- radiotherapy; and
- radiology.

The hospital may however, designate a departmental RSO who will be responsible for the day-to-day radiation safety within one department. In a radiology department, the departmental RSO may be:

- a qualified expert (see section 3.6);
- an experienced radiographer; or
- a radiologist.

3.6 QUALIFIED EXPERT

Clause 3.1.24 of the Code requires that a Qualified Expert be available:

- for consultation on optimisation of medical exposures, including clinical dosimetry and quality assurance; and
- to give advice on matters relating to radiation protection.

The qualified expert will have suitable qualifications and experience in radiological physics. A medical physicist with specialist experience in radiology – a **radiology medical physicist** – would satisfy these requirements. This person may be an employee or an external consultant and may also be appointed as the RSO with the additional responsibilities outlined in section 3.5.

The radiology medical physicist should work closely with the radiologists and radiographers to optimise clinical studies through:

- image acquisition;
- analysis;
- display optimisation; and
- ongoing oversight of the quality control of equipment.

In many smaller practices, an experienced radiographer or radiologist may also undertake some of these duties. The radiology medical physicist's responsibilities should extend to image quality assessments in conjunction with other medical staff, where appropriate.

The requirement to have a radiology medical physicist oversee the QC tests performed under the Royal Australian and New Zealand College of Radiologists (RANZCR) and BreastScreen Australia (BSA) mammography accreditation programs is an example of this type of involvement (RANZCR 2002, BSA 2002).

As part of the QA program, the radiology medical physicist should also:

- periodically undertake patient dose estimates;
- compare patient doses with published diagnostic reference levels (DRLs), where relevant; and
- recommend the action that needs to be taken if the patient doses are deemed to be unacceptable (ICRP 1996).

Radiation | 3.6.1 Exposure from Research Studies

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In accordance with the requirements of RPS8 (ARPANSA 2005a), a medical physicist or radiology medical physicist needs to provide Human Research Ethics Committees with:

- an estimate of radiation dose; and
- an assessment of the risk,

to all participants exposed to ionizing radiation for research purposes.

Safety Guide Radiation Protection in Diagnostic and Interventional Radiology

4. Optimisation of Protection for Medical Exposures

4.1 GENERAL CONSIDERATIONS

Once clinically justified, each examination should be conducted so that the dose to the patient is the lowest necessary to achieve the clinical aim. The quality of the images and the complexity of the examination should be sufficient for the intended purpose of the procedure. Since patients may accrue direct benefits from medical exposures, it is not appropriate to impose strict limits on the doses received from fully justified examinations. However, patient dose surveys indicate wide variations in delivered dose to achieve satisfactory image quality indicating that there is significant scope for the implementation and optimisation of patient protection (NRPB 1999). The Code therefore requires that the Responsible Person implement DRLs as a practical, quantitative guidance tool to aid in dose optimisation (see also section 7.8 of this Safety Guide).

Clauses 3.2.7, 3.2.8 and 3.3.6 of the Code highlight the need for individuals performing or directing exposures to ionizing radiation to take particular care when irradiating pregnant or potentially pregnant women. This should extend beyond the mere selection of **exposure factors**. In order to achieve this, operators should take extra care:

- choosing appropriate radiographic views, angles and collimation that avoid or minimise the irradiation of the uterus or fetus with the primary beam; and
- avoid fluoroscopy, particularly of the abdomen or pelvis, where possible.

In general, the optimisation process necessarily requires a balance between patient dose and image quality and it is important that diagnostic quality of the image is not lost in the cause of dose reduction. Images of unacceptable quality can result from unwarranted reductions in patient dose rendering the images un-diagnostic and ultimately leading to repeat examinations and higher patient doses. The clinical problem will dictate the requirement for image quality and lower image quality might be acceptable in some circumstances. Further, the size and shape of the patient will influence the level of dose required. Accordingly, clause 3.3.4 of the Code requires that the operator of radiographic equipment minimise patient dose under the constraint that the image quality is acceptable for the diagnostic information being sought. Thus, the operator should:

- tailor the kVp, beam **filtration** and mAs to the patient's specific anatomy;
- restrict the number of views per examination to the minimum necessary;
- choose the most efficient image receptor required to achieve the diagnostic information (e.g., fast versus slow intensifying screen speed, correct matching of film and screens);
- avoid the universal use of anti-scatter grids, most particularly in the context of radiography and fluoroscopy of patients under the age of 18 years;

- collimate the primary X-ray beam to within the size of the image receptor in use and only to the clinically relevant region of interest. This has the added benefit of simultaneously improving image quality and lowering dose;
- avoid the use of extremely short source to image distances as this can lead to unnecessarily high skin doses;
- shield radiosensitive organs such as the gonads, lens of the eye, breast and thyroid whenever feasible. Note that where the use of shielding will obscure the desired information relevant to the examination (e.g. ovarian shields in an abdominal X-ray) the use of such shielding is discouraged. Further, it should be appreciated that protective drapes do not guard against radiation scattered internally within the body and only provide significant protection in cases where part of the primary X-ray beam is directed towards structures outside the immediate area of interest;
- optimise film processor function (e.g., chemistry, developer temperature, replenishment rate and dwell time) according to the manufacturer's recommendations; and
- exercise extra care when using digital radiography systems with wide dynamic ranges, such as Computed Radiography (CR) and flat panel detectors. Choosing the appropriate image processing parameters is just one aspect of the procedure that the operator needs to consider. Patient dose may be increased to excessive levels without compromising image quality in the phenomena known as 'exposure creep' (Heggie & Wilkinson 2000, ICRP 2004) and it is therefore recommended that AEC devices be utilised with digital imaging systems.

Of particular note are the European guidelines (EU 1996a, EU 1996b), which have been developed to provide specific advice on good technique when radiographing paediatric and adult patients, respectively.

The patient and the operator will be unnecessarily exposed to radiation if a radiographic procedure needs to be repeated. Generally, the operator will need to make a repeat exposure if the image:

- is poor quality; or
- does not provide the clinical information required.

To minimise the chance of making repeat exposures, the operator should:

- plan the examination carefully to fit the clinical problem;
- ensure the patient is positioned correctly with respect to the image receptor and X-ray tube; and
- avoid technical errors by correctly selecting the:
 - exposure factors consistent with the anatomical region under examination;
 - speed of the image receptor; and,
 - processing procedures, where relevant.

If AEC is not available, technique charts should be posted for the common radiographic examinations to assist in maintaining proper image quality. A comprehensive Quality Assurance program (see section 7 of this Safety Guide), which includes reject analysis, should highlight systematic errors or problems and ultimately lead to a lower repeat rate. The institution should keep a record (electronic or manual) of all digital images taken. In any event, repeat exposures should not be undertaken simply because an image may not be of the highest quality. If the image contains the required information then a repeat exposure should not be performed.

4.2 FLUOROSCOPIC EXAMINATIONS

The prescription of what constitutes optimal techniques may be difficult to define for complex examinations that use fluoroscopy as well as static imaging such as:

- barium studies;
- angiography; and
- interventional radiology,

In many instances, the conduct of the examination is unique to the patient. Nevertheless, the operator of any fluoroscopic equipment still needs to use dose reduction strategies. A list of 'commandments for reducing dose' in fluoroscopic examinations has been enunciated by Wagner and Archer (2000) and the ICRP (ICRP 2000a) and is recommended for adoption. This list is reproduced in modified form below:

- use **automatic brightness control** (ABC), low frame rate, pulsed fluoroscopy, and last image hold (LIH) routinely when they are available;
- optimise the radiographic geometry (i.e. avoid geometric magnification) as poor technique combined with poor geometry can cause patient skin doses to be unnecessarily elevated such that deterministic effects may occur. The X-ray tube should be kept at maximum distance from the patient and the imaging receptor as close to the patient as possible;
- use the largest image intensifier or flat panel field size collimated down to the region of interest that is consistent with the imaging needs. That is, avoid electronic magnification (i.e. use of small field sizes). Electronic magnification results in dose rates to the patient that may be several times higher than those that apply when the largest field size is chosen;
- choose the lowest dose rate options available commensurate with image quality requirements. This may mean keeping tube current as low as possible by keeping the tube voltage as high as possible or using pulsed fluoroscopy if it is available;
- avoid the universal use of anti-scatter grids. Remove the grid when examining small patients or when the imaging device cannot be placed close to the patient;
- minimise the fluoroscopy time. However, operators should be aware that elapsed fluoroscopy time is not a reliable indicator of dose. Patient size and procedural aspects such as locations of the beam, beam angle, image

receptor dose rate, and the number of acquisitions can cause the maximum skin dose to vary by a factor of at least ten for a specific total fluoroscopy time;

- choose the lowest frame rate and shortest run time consistent with diagnostic requirements during digital image acquisition procedures (e.g. digital subtraction angiography (DSA) and cardiac angiography);
- consider employing additional strategies including the use of additional or k-edge beam filtration, and radiation-free collimator adjustment whenever possible;
- consider options for positioning the patient or altering the X-ray field or other means to alter the beam angulation when the procedure is unexpectedly long so that the same area of skin is not continuously in the direct X-ray field (skin sparing); and
- be aware that dose rates will be greater and dose will accumulate faster in larger patients. However, the work of Marshall *et al* (Marshall *et al* 2000) highlights the fact that in complex procedures, operator choices and clinical complexity are more likely to affect patient dose than the physical size of the patient.

4.3 INTERVENTIONAL PROCEDURES

Dose reduction strategies outlined in part 4.2 above are particularly pertinent in the conduct of interventional procedures where the possibility of inducing severe deterministic effects has been highlighted by the ICRP (ICRP 2000a), the World Health Organization (WHO 2000) and others (see for example, Wagner and Archer 2000). Since the early 1990's there has been a steady increase in the number of reports of radiation-induced skin injury to patients (see for example the summaries provided in ICRP 2000a, Koenig et al 2001a and 2001b). Australia and New Zealand literature has also reported injuries of this type. It is likely that the reported frequency represents only a small fraction of the incidence; evidence of radiation-induced skin injury is only usually observed well after the patient has left the interventionist's care. The injuries from interventional procedures span the whole spectrum from temporary erythema and hair epilation to tissue necrosis, the latter requiring extensive skin grafts over of a period several years. The increasing number and complexity of interventional procedures will no doubt, exacerbate these problems in the future.

Most interventional procedures are used to treat life-threatening conditions. Nearly all radiation induced injuries, and all of the serious ones, can be prevented without compromising the efficacy of the procedure (ICRP 2000a). Unsurprisingly, there have been cases of successful litigation against practitioners in the United States. The ICRP has also noted that the potential for stochastic effects from interventional procedures exists given the increasing number of young and middle aged patients. A note should be included in the report to the referrer that they should be aware that their patient might present with radiation induced skin damage later. To lower the potential for skin damage, the ICRP has stressed the importance of developing a local clinical protocol for each type of interventional procedure and has therefore recommended the implementation of this policy. The protocol should include:

- a statement on the 'expected' radiographic images including:
 - projections;
 - number; and
 - technique factors; and
- the 'nominal' values for:
 - fluoroscopy times;
 - air kerma rates; and
 - resulting cumulative dose at each skin site exposed.

A radiology medical physicist or equivalent expert should be able to assist in obtaining this information. These numbers should relate to the fluoroscopy equipment installed at the facility. Each case may vary considerably and the protocol should act only as a baseline for the procedure. Annex C of ICRP 85 (ICRP 2000a) provides an example of a complete clinical protocol, in this case, for a transjugular intrahepatic porto-systemic shunt.

4.4 CT EXAMINATIONS

Generally, technical and clinical developments in CT have not led in general to reductions in patient dose per examination, in contrast to the trend in conventional radiology. Coupled with an increased use of CT in diagnosis in most developed countries (ICRP 2000c, UNSCEAR 2000) there are increased concerns about:

- the magnitude of the doses that arise from CT examinations; and
- the potential risks that these imply.

Data about the Japanese bomb survivors (Preston *et al* 2003) suggest that doses typical of CT examinations pose a risk of cancer induction. This is particularly true of CT examinations of paediatric patients, who may also be at greater risk from stochastic effects than the general population (Brenner *et al* 2001). Further, repetitive CT examinations (e.g., multi-phasic contrast) have the potential to result in **absorbed doses** in tissues that may approach or even exceed the threshold for deterministic effects. Accordingly, all common CT procedures should follow established protocols. In order to jointly optimise patient dose and image quality, the operator of a CT scanner should tailor the technical factors of the examination (kVp, mAs, nominal collimated X-ray beam width, **pitch**, volume of patient scanned) to the:

- individual patient anatomy; and
- diagnostic information being sought (EU 1999, EU 2004, ICRP 2000c, ICRP 2001, ICRP 2007).

For a particular patient, all other factors being kept constant, the patient effective dose will increase in direct proportion to the mAs and inversely to

the pitch. Accordingly, with single slice scanners it has been good practice to choose the highest value for the pitch and the lowest value of the mAs consistent with obtaining the required clinical diagnosis. Since a pitch value of less than one is analogous to overlapping scanning in sequential mode, pitch values have usually been chosen in the range of one to two and only in exceptional circumstances should they be less than one. With multi-slice scanners, some manufacturers have tied the selection of mAs and pitch together so that the ratio of the mAs to pitch remains constant when the pitch is altered. Under these circumstances, changing the pitch has little impact on patient dose and pitch values of less than one may be safely used.

As an example of the customisation that can be achieved, Boone *et al* (2003) have produced patient size dependent technique charts based on phantom simulations for one model of a multi-slice scanner. For a paediatric, abdominal CT scan, the same image quality (contrast to noise ratio kept constant) can be maintained using less than 5% of the value used for a typical adult. The resulting effective dose reduction is almost as impressive. Boone *et al*'s work also suggests similar optimisation is possible when performing head CT scans on children. McLean *et al* (2003) has highlighted the need for vigilance in establishing CT scan protocols for paediatric patients in Australia.

The European Commission has developed quality criteria (EU 1999, EU 2004) that result in recommendations concerning achievable standards of good practice for CT. These documents provide an operational framework for radiological protection initiatives in which technical parameters for image quality are considered in relation to patient dose. Diagnostic and dose requirements for CT are specified in terms of the quality criteria considered necessary to produce images of standard quality for a particular anatomical region. The subjective image criteria include anatomical criteria that relate to the visualisation or critical reproduction of anatomical features. DRLs associated with the examination technique used for standard-sized patients outline the criteria concerning patient dose. Quality criteria have been developed for most examinations, together with examples of technique parameters influencing the dose.

Multi-slice CT scanners offer a number of clinical advantages, but because of a combination of their unique design characteristics and superior scanning speed, are capable of delivering high patient doses (EU 2004, ICRP 2000c, ICRP 2001, Nagel *et al* 2002, ICRP 2007) unless technical factors are carefully selected by the operator. Practitioners should be mindful that manufacturers of multi-slice CT scanners intend that the Radiation Medical Practitioner modify the default protocols to optimise the image quality/patient dose relationship. Substantial dose reductions without loss of diagnostic image quality can be achieved for even the average patient, by tailoring the technical parameters used in an examination (Nagel *et al* 2002, Heggie 2005, Heggie *et al* 2006).

4.5 **PROTECTIVE DEVICES FOR THE PATIENT**

During radiological procedures, the operator should provide protection to the patient for radiosensitive organs such as the:

- gonads;
- lens of the eye;
- breast; and
- thyroid.

Gonad shields should have a minimum **lead equivalence** of 0.5 mm (at 150 kVp) but in addition, they should also meet other design specifications outlined in the Australian Standard (AS/NZS 2000a). The operator should also consider using thin bismuth breast shields during CT examinations as studies have demonstrated substantial breast dose reductions without compromising diagnostic image quality (Hopper *et al* 1997, Fricke *et al* 2003). Bismuth eye shields may also be useful in minimising the dose to the lens of the eye during head CT examinations (Hopper *et al* 2001).

- **Note 1:** Bismuth breast shields are unlikely to result in patient dose savings with modern CT scanners that utilise anatomy dependent, attenuation based methods of **X-ray tube current** modulation since the presence of the lead in the primary beam will drive the tube current higher than it might otherwise be.
- **Note 2:** Where the use of shielding will obscure the desired information relevant to the examination the use of such shielding is discouraged.
- **Note 3:** In some instances (e.g., the covering of the female abdomen during a chest CT scan or general radiographic procedure), the use of lead shielding is more for patient reassurance than for any real physical benefit as the major source of exposure to the abdominal organs is by way of internal scatter.

5. Pregnancy and Protection of the Embryo/Fetus

Radiation risk is related to the:

- fetal effective dose; and
- stage of pregnancy (ICRP 2000b, Sharp *et al* 1998).

The most significant risk is during organogenesis. The main risks (although low) are childhood cancer and leukaemia. Most diagnostic radiology procedures pose little risk to the mother or fetus, when compared with other risks throughout the pregnancy. However, interventional radiology procedures involving extended fluoroscopy times, and CT scans of the abdomen or pelvis may result in:

- a significant fetal dose; and
- an increased risk of cancer.

Nevertheless, it is unlikely that the fetal effective dose from diagnostic or most interventional procedures will exceed 100 millisievert, when nervous system abnormalities, malformations, growth retardation and fetal death are possible (ICRP 2000b, Sharp *et al* 1998).

Clause 3.1.18 of the Code requires that the Radiology Department has illustrated signs in prominent places advising patients to notify staff if they may be pregnant. Ideally, these signs will be written in several languages relevant to the community. An example might read as follows:

IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT, NOTIFY THE PHYSICIAN OR RADIOGRAPHER BEFORE YOUR X-RAY EXAMINATION.

However, the posting of signs in no way absolves the operator or the Radiation Medical Practitioner of their responsibility to enquire about the possibility of pregnancy in all female patients of childbearing age. When asking the patient about the possibility of pregnancy it is also important to indicate to the patient why there is a need to know, to avoid them taking offence and refusing to answer or answering less than truthfully. When language barriers exist, it may be useful to seek the service of an appropriate interpreter.

The Radiation Medical Practitioner should consider the amenorrhea occurring in a patient, who usually has regular periods, is due to pregnancy unless proved otherwise. In any event, when doubt exists about the pregnancy status of an individual woman and moderate or high doses to the lower abdomen are involved, the Radiation Medical Practitioner should consider serum β -HCG testing before medical exposure.

General radiographic examinations of the extremities, head and skull, mammography and CT examinations of the neck and head can be undertaken on pregnant or possibly pregnant women without concern. The operator should provide a leaded drape to cover the lower abdomen in such circumstances although it is as much for psychological reasons as for any physical benefit. Other radiological examinations may also be undertaken if the radiation dose to the embryo or fetus is likely to be less than 1 mSv. Annex A provides information on the likely doses that may be useful to clinicians in this regard.

Individual patient fetal dose estimates may be required in some circumstances. This would normally require the services of a radiology medical physicist but some practitioners may find the advice on fetal dose estimation provided by Wagner *et al* (Wagner *et al* 1997) a convenient resource. Alternately, the fetal dose estimates provided by Sharp *et al* (Sharp *et al* 1998) may be sufficient in many instances. In any event, dose estimations will require knowledge of technical factors such as kVp, mAs, field size, source skin distance, filtration etc. and practices should be encouraged to record this type of data as a matter of course.

The Radiation Medical Practitioner or, less ideally, the referrer needs to advise a pregnant patient, where possible and appropriate to the procedure, of the potential risks to the embryo/fetus associated with in-utero exposure. In order to do this, the Radiation Medical Practitioner or referrer should be familiar with the effect of ionizing radiation on the embryo and fetus and be able to communicate the significance of any risks to the patient in a meaningful manner.

6. Equipment

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6.1 GENERAL REQUIREMENTS

All diagnostic and interventional X-ray equipment used in Australia will need to be registered or listed with the Therapeutic Goods Administration (TGA) and will therefore need to meet relevant international and national safety standards. Further, the *National Directory for Radiation Protection* will contain uniform national testing criteria for certain classes of medical X-ray equipment.

Additionally, the equipment should be clearly and accurately marked with:

- the X-ray tube inherent filtration;
- the focal spot position;
- any added filtration in the tube housing or collimator;
- the source to image receptor distance (where appropriate); and
- the image field size.

Ideally, the operating terminology (or their abbreviations) and the selected technique factors should be clearly and unambiguously displayed on operating consoles before the exposure is initiated. For AEC systems, this requirement is met if the technique factors are clearly displayed immediately following the completion of the exposure.

Radiation beam control mechanisms should be provided, including devices that indicate clearly, and in a fail-safe manner, whether the beam is 'ON' or 'OFF'.

All diagnostic and interventional X-ray equipment used in either the direct or indirect radiographic mode (as opposed to the fluoroscopic mode) should be fitted with a device that automatically terminates the irradiation after a preset:

- time;
- tube current-time product; or
- dose.

Except in special techniques, such as angiography, it should not be possible to make repeat exposures without releasing the exposure initiating control.

It is important that all X-ray equipment prevents emission of radiation before the initiation and after the termination of the exposure. This requirement is particularly pertinent to capacitor discharge units. These units can maintain a high voltage across the X-ray tube for some time after the exposure has terminated. Accordingly, these latter units should be equipped with electronically interlocked (dark) shutters to prevent the unintended emission of radiation. With the exception of mammography and CT equipment, all diagnostic and interventional X-ray equipment need to be fitted with continuously adjustable beam collimating devices. Such devices allow the operator to limit the area being imaged to the:

- size of the selected image receptor; or
- region of interest, whichever is the smaller.

To facilitate this task, the operator should use a 'light beam' collimator whenever practicable.

6.2 SPECIALISED EQUIPMENT

All diagnostic equipment used in the fluoroscopic mode need to limit the maximum air kerma rate at a position representative of the patient's skin entrance. The relevant Australian and New Zealand Standard (AS/NZS 1999) specifies conditions under which the maximum air kerma rates should be measured for various types of fluoroscopic X-ray equipment.

The Standards require that all diagnostic X-ray equipment used in the fluoroscopic mode be equipped with safety features. This requirement may be met if the equipment incorporates:

- a device that energises the X-ray tube only when continuously depressed (such as a dead-man switch²);
- an indicator of the elapsed fluoroscopic exposure time per patient; and
- for conventional under couch X-ray tube designs, adjustable lead drapes of lead equivalence of not less than 0.5 mm (at 150 kVp), mounted on the image intensifier or flat panel detector support.

Additional dose reduction features are required for new fluoroscopy equipment and highly desirable for existing equipment.

Future editions of the international and Australian/New Zealand standards may require the fitting of DAP meters to fluoroscopy units to facilitate dose estimations. Therefore, all new fluoroscopy units should be fitted with these devices. All equipment used for relatively high dose procedures such as, but not limited to:

- cardiology;
- angiography;
- interventional work; and
- vascular surgical work,

should be equipped with DAP meters.

For fluoroscopic examinations, the **conversion factor** (gain) of the image intensifier is one of the key factors in determining doses (NRPB 1999). High

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² A switch used to initiate an X-ray exposure that will automatically terminate the exposure when released.

conversion factor image intensifiers operated with ABC can produce acceptable diagnostic quality images at dose rates to the input of the image intensifier of approximately 0.1-0.2 μ Gy/s. Unfortunately, the conversion factor decreases with time and it will therefore be necessary to replace the image intensifier when the gain falls below a level at which patient doses are deemed to be unacceptably high.

Interventional and some angiographic examinations have the potential to cause skin damage. Thus, the Standard (AS/NZS 2002a) outlines features that are:

- required for X-ray units used explicitly for interventional radiology; and
- desirable to have on any fluoroscopic equipment.

Additionally, such equipment should be equipped with a DAP meter or similar device. Such devices enable the operator or Radiation Medical Practitioner to determine of the ESD and dose rate at a reference point indicative of the patient's skin entrance. The integrated dose at the reference point:

- should be recorded in the patient' medical record at the end of the procedure; and
- may serve as an indicator to the practitioner of the potential for any subsequent skin damage.

Equipment used for mammography will also need to meet the technical requirements of the RANZCR and BreastScreen Australia mammography accreditation programs (RANZCR 2002, BSA 2002, McLean *et al* 2007).

6.3 NEW EQUIPMENT

The procurement of equipment for interventional radiology is a critical part of the process of dose control (ICRP 2000a). The purchase of inappropriate or inadequate equipment would not meet the dose optimisation obligations of the Code. Additionally, X-ray equipment for interventional radiology is expensive and represents a considerable capital investment by the radiological practice. With increasing financial pressures on health care budgets, it is vital that inferior equipment, which:

- does not meet clinical requirements; and
- results in high patient and occupational doses,

is not acquired because of financial constraints.

Consequently, the specification, procurement, and commissioning of equipment for interventional radiology is crucial to a dose control strategy and such equipment should include:

- any available radiation protection attachments; and
- patient dose monitoring features.

Accordingly, when purchasing fluoroscopy equipment to be used for interventional radiology, the requirements of AS/NZS 3200.2.43 (AS/NZS 2002a) need to be met. Specifically, the Standard requires that the equipment provide:

- ergonomically convenient radiation protection devices (drapes, lead glass screens etc.);
- pulsed fluoroscopy;
- other dose reduction features (e.g., selectable filtration options); and
- most importantly, an appropriate indication of dose rate and/or dose at a reference point indicative of the patient's skin entrance.

New CT scanners, in accordance with AS/NZS 3200.2.4 (AS/NZS 2005), should display the value of the volume **computed tomography dose index** (CTDI_{vol}) and preferably the **dose-length product** (DLP) on the operator's console after the selection of technique factors and prior to the initiation of X-rays. The CTDI_{vol} reflects the:

- type of examination selected, head or body; and
- CT conditions of operation.

The $\mbox{CTDI}_{\mbox{vol}}$ and DLP should be recorded as they may be used for comparison with DRLs.

Radiation
Protection7.Quality Assurance

7.1 GENERAL

Clause 3.1.21 of the Code requires that each radiology practice establish a Quality Assurance (QA) program, which places emphasis on image quality optimisation and patient dose reduction. The extent of the QA program will depend on the complexity and resources of the radiological practice. At the very least, it should address the issues outlined in the subsequent clauses and have a well-defined responsibility and reporting structure. The elements of the QA program outlined below include a system of checks and procedures to ensure that the aims of the QA program enunciated above are met.

The Responsible Person should seek the advice of a qualified expert on matters relating to:

- image quality optimisation;
- patient dosimetry;
- quality assurance (IAEA 2002); and
- other matters relating to radiation protection as required.

7.2 ACCEPTANCE TESTING OF X-RAY EQUIPMENT

At initial installation, an appropriately authorised tester should carry out a series of acceptance tests on:

- the diagnostic or interventional radiology equipment; and
- associated equipment (e.g. film processors, Computed Radiography reader).

The relevant Australian and New Zealand Standards (e.g. AS/NZS 2002b) or other publications by professional bodies (e.g. IPEM 2003, AAPM 2002) can provide some indication as to the type of testing that may be undertaken. A qualified person, preferably a radiology medical physicist, may use these tests to verify that the initial performance of the equipment conforms to the manufacturer's specifications and to Australian and New Zealand Standards. The person testing the equipment should thoroughly document the results of the acceptance tests as those results might be used in part to define the acceptable range of parameters that will be monitored in any subsequent **constancy testing**.

7.3 CONSTANCY TESTING OF X-RAY EQUIPMENT

Following acceptance, a suitably qualified person, such as a radiographer, should perform constancy tests designed to assess:

- the subsequent performance of the equipment;
- image quality; and
- patient dose.

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System tests using appropriate image quality phantoms should form the basis of constancy tests and are usually less involved than acceptance tests. The ICRP (ICRP 2004) has identified the need for different constancy and acceptance tests when digital radiography equipment is utilised.

An appropriate person with the Department should:

- routinely review the results of constancy testing; and
- report any anomalous results immediately to the person responsible for the QA program management.

When the results of constancy tests indicate that the equipment is outside tolerance, the results, in extreme circumstances, may be used to justify replacement of equipment. For example, the efficiency of an image intensifier deteriorates with time due to:

- loss of vacuum; and
- radiation damage to the output phosphor.

At some point, this loss of efficiency will be sufficiently severe that the dose to the patient will exceed acceptable levels and replacement is essential.

7.4 **TESTING FREQUENCY**

The Australian and New Zealand Standards (e.g. AS/NZS 2002c) and other publications (e.g. IPEM 2003, AAPM 2002) outline how often tests should be carried out. In any event, the frequency with which any particular parameter is assessed should take into account the:

- likelihood of an equipment failure or a measured parameter falling outside an acceptable tolerance range; and
- consequences that follow when such an event occurs. For example, film processor performance should be monitored frequently as the developer chemistry is difficult to control and any changes may have a substantial impact on both image quality and patient dose.

7.5 FILM PROCESSING

For radiology departments that print film, the film processor is the most important factor in relation to constancy testing. Substantial changes in image quality and patient dose may occur through subtle changes in the:

- processor chemistry;
- replenishment rate;
- temperature; and
- development time.

As such, a suitably qualified person should regularly carry out sensitometry and densitometry measurements on the processor. Daily testing is required for mammography (RANZCR 2002, BSA 2002) with less stringent regimes needed for other applications. Investigative action is warranted to determine

the cause of any problem where established tolerance levels are exceeded. A qualified person should investigate any artefacts that appear on the test films.

7.6 IMAGE REJECT ANALYSIS

A senior radiographer should investigate the reasons for rejecting images, whether produced on film or in digital form (Honea *et al* 2002), as such an analysis is a fundamental aspect of the QA program. Errors of positioning and image labelling may emerge that can be remedied by appropriate instruction. Over or under exposure errors may indicate, for example, that there is:

- a fault with a particular X-ray tube in a particular room; or
- a mismatch of film-screen combinations.

It is important to note that reject analysis is an educative rather than a punitive process. Cooperation, not alienation of radiographers and others, is a key to a successful QA program.

7.7 **RECORD KEEPING**

Another key element of any QA program is proper record keeping so that any long-term trends associated with a particular item of equipment can be identified and acted on before image quality and/or patient dose are compromised. Control charts:

- plot the behaviour of a measured parameter as a function of time; and
- represent a convenient way to keep records of constancy tests.

In any event, such record keeping should at least extend to noting:

- the results of **acceptance testing**;
- the results of any constancy tests;
- the results of reject analysis; and
- equipment unscheduled downtime and the reason for the failure.

The question of how long QA records should be maintained is a matter of some debate. However, to protect against possible future litigation, the Responsible Person should keep records of acceptance and constancy testing for the life of the equipment. The final decision about record keeping will depend on the judgement of the individual institution.

7.8 PATIENT DOSE SURVEYS AND DIAGNOSTIC REFERENCE LEVELS (DRLS)

As part of the QA program, the Responsible Person should make sure that patient dose surveys are undertaken periodically to establish that the doses are acceptable when compared with published DRLs. Accrediting bodies, such as the RANZCR and the Australian Council on Healthcare Standards, should consider including compliance with DRLs for a core set of examinations as one element in achieving accreditation to encourage institutions to perform dose surveys (NRPB 1999). In any event, an institution needs to take action if patient doses are unacceptable (ICRP 1996). Repeatedly and substantially exceeding the DRLs might indicate an underlying fundamental problem that warrants investigation. However, DRLs should be applied with flexibility to allow higher doses if these are indicated by sound clinical judgement (IAEA 1996). Further, patient dose surveys and image quality assessments should always be undertaken together.

There are some technical matters relating to DRLs that should be borne in mind:

- Institutions should establish their own local DRLs and compare patient doses with these values at appropriate intervals (George *et al* 2004). In Australia, the relevant professional societies in consultation with relevant regulatory authorities will establish national DRLs for both adults and paediatric patients for most common examinations. The Institution should set local DRLs with due regard to these national DRLs where they are available;
- The DRLs for adults are usually defined for a person of average size (about 70 to 80 kg). When performing dose surveys, patients within this weight range should be selected;
- Recommended values for DRLs are frequently chosen as a percentile point (typically the 75% level) in a substantive survey of the observed distribution of doses to patients. They do not represent best practice and therefore, the ultimate target for any institution should be to lower their doses to a level regarded as achievable. For any procedure, an achievable dose is one which maximises the difference between the benefit and risk without compromising the clinical purpose of the examination (NRPB 1999);
- The relevant regulatory authorities, in consultation with the relevant professional societies, should review and adjust DRL values at intervals that represent a compromise between:
 - the necessity for stability; and
 - long term changes in the dose distributions arising from technological improvements.

Usually, the DRL is lowered as a result of technological improvements and the difference between DRLs and achievable doses is likely to narrow with the passage of time;

- The choice of dose descriptor to use as a DRL depends on the type of examination. The DRL should be expressed as a readily measurable patient-related quantity for the specified procedure and usually for:
 - general radiographic examinations, it is taken to be either the ESD or the DAP;
 - fluoroscopic examinations, it is taken to be the DAP; and
 - CT examinations, it is taken to be the DLP; and

Radiation
Protection•DRLs established for film-screen technology should not necessarily be
carried over without adjustment when digital radiography technologies
are adopted (ICRP 2004). Further, the ICRP have highlighted the need to
perform patient dose surveys more frequently with digital modalities to
establish that 'exposure creep' is not occurring.

8. Radiation Incidents

8.1 GENERAL CONSIDERATIONS

Those investigating incidents arising from diagnostic or interventional radiology procedures should aim at:

- establishing what happened;
- identifying the failure of equipment or processes;
- deciding on remedial action to minimise the chance of a similar failure; and
- estimating the likely doses received by the patient and the operator.

Internal reports of all incidents should be prepared and referred to for educative purposes during reviews and training sessions.

As a matter of good practice, where a patient is involved in an incident arising from a diagnostic and radiological procedure, the Radiation Medical Practitioner or referrer should:

- advise the patient about the event; and
- counsel that patient as to the likely implications of the unintended exposure, unless there is a good reason for not doing so.

The decision as to when and by whom the patient is notified may be made locally but at the very least either the Radiation Medical Practitioner or the referrer should be involved.

When the patient is unable to comprehend the information given, it may be more appropriate to inform the patient's representative or parent/guardian.

The Code identifies particular instances when the relevant regulatory authority needs to be notified. However, it would also be sensible to notify the relevant regulatory authority of any instances where X-ray equipment failure has contributed directly to a patient or operator receiving an unnecessary dose.

8.2 INTERVENTIONAL PROCEDURES

Many interventional procedures are sufficiently complex that unexpected skin damage may occur in patients following prolonged exposures. Under these circumstances, institutions should report any such abnormal outcomes to the relevant regulatory authority. The reporting process is not intended to be punitive but instead, will allow others to be advised or forewarned that such undesirable outcomes may be possible unless extreme care is exercised. This is an essential component in the development of a sound radiation safety culture. The operator should monitor the value shown on a DAP meter, where fitted, during a procedure to forecast possible skin damage that may occur.

Radiation	Protracted exposures may also cause damage to the eyes (Vano et al 1998a,
Protection	Haskal and Worgul 2004) and skin of interventionalists (Wagner and Archer
Series	2000). The institution should make sure that any such occurrences are
No. 14.1	reported to the relevant regulatory authority.



9. Occupational Exposure

9.1 GENERAL CONSIDERATIONS

The radiation dose to the operator can be minimised by:

- prudent positioning relative to the:
 - X-ray tube;
 - patient; and/or
- structural shielding.

Where there is no structural shield and the operator has to remain in the room during general radiography, such as with mobile radiography, the operator should stand:

- at least two metres away from the X-ray tube; and
- outside the primary beam.

In these circumstances the operator should, at the very least, wear protective lead aprons.

Where a person is required to be present in a controlled area³ during an X-ray exposure, such as in a fluoroscopy suite, that person should not remain any closer to the patient or the X-ray tube than is necessary. The operator should ensure that any person who is required to remain in the room during the radiation exposure:

- wears protective clothing; or
- stands behind protective shields.

The design of all radiology suites should include a protected area in which the operator's console is located. The operator's console should be the only area within the radiology suite that radiography and remote controlled fluoroscopy systems (usually over-table X-ray tube systems) are operable.

Schedule A1.1 of the Code requires that the Responsible Person provide personal safety and protective devices for employees involved in:

- radiography with mobile equipment;
- fluoroscopy; or
- interventional procedures.

Lead aprons, thyroid shields and other personal protective devices should meet minimum design criteria as outlined in the Australian Standard (AS/NZS 2000a). Although lead aprons should be of at least 0.25 mm lead equivalence (at 150 kVp), in practice, their thickness should be selected with due consideration given to the type of workload being undertaken. Individuals continually involved in interventional radiology should wear

³ An area to which access is subject to control and in which employees are required to follow specific procedures aimed at controlling exposure to radiation.

aprons of at least 0.35 mm lead equivalence (at 150 kVp) if not 0.5 mm lead equivalence (at 150 kVp). Preferred designs are those comprising a separate vest and skirt that wrap around fully, as open back designs are not recommended.

Operators and other staff should use thyroid shields in all cardiology and interventional radiology suites. Further, the Responsible Person should provide all relevant staff with protective gloves for use during all radiological procedures in which the hands and forearms may be in the primary beam.

All personal protective clothing should be:

- clearly labelled with its lead equivalence as specified by the Australian Standard; and
- examined under fluoroscopy at least annually to confirm its shielding integrity.

If an occupationally exposed member of staff is pregnant and the pregnancy has been declared to the **employer**, clause 3.1.10 of the Code requires that the fetus be afforded the same level of protection as a member of the public. Therefore, the fetus should not receive a dose greater than the public effective dose limit of 1 mSv per year for the remainder of the pregnancy. Despite other psychological issues that the pregnant staff member may have, it is usually not necessary to modify work practices during pregnancy. The Responsible Person should however provide an occupationally exposed pregnant staff member with a personal dose monitor if she does not already have one.

Wherever possible, the operator should fix the image receptor in position by using an image receptor holder. In rare circumstances where the image receptor is unable to be fixed into position, the patient or, if the patient is incapacitated, an individual not routinely exposed to ionizing radiation should hold the image receptor.

In some cases, it may be necessary for a person to restrain an uncooperative patient (e.g. a child or incapacitated patient) during an exposure. Where such a situation arises, the operator should use restraining devices as a first preference. If this is not possible, someone not occupationally exposed to radiation, such as a carer, should restrain the patient.

In some fluoroscopic procedures, it may be necessary for the operator to place their hands in the primary beam. In these circumstances, the operator should consider wearing leaded gloves.

There are no foreseeable circumstances during an X-ray exposure, however, where a person would need to hold:

- any part of the X-ray tube head; or
- the image receptor,

in position either by hand or with any instrument not designed for the purpose. As such, this practice is to be avoided.

9.2 CT FLUOROSCOPY

CT fluoroscopy has the potential to result in high doses to the hands of any person performing CT fluoroscopy procedures and the operator therefore needs to consider carefully the issue of radiation protection. In fact, it is very easy to exceed the dose limits for the extremities for a realistic caseload (Kato *et al*, 1996). Some manufacturers have developed new technology allowing the X-ray tube to be switched off as it rotates above the patient thus helping to reduce the dose to the practitioner.

Since wearing leaded gloves may result in a loss of dexterity, this option may be untenable in some CT fluoroscopy procedures. Accordingly, practitioners should use specially designed forceps and/or needle holders to aid in dose minimisation to their fingers (Kato *et al*, 1996).

Lead drapes placed two centimetres caudal to the scan plane will dramatically reduce the dose to the hands and abdomen of radiologists (Nawfel *et al* 2000). Practitioners performing CT fluoroscopy should therefore use this dose reduction technique although this in no way absolves the practitioner from the need to wear protective clothing.

9.3 INTERVENTIONAL RADIOLOGY

Substantial occupational exposure may arise during interventional procedures due to:

- inappropriate equipment; and
- inadequate personnel protection (Johnson *et al* 2001).

The major source of this exposure is scatter radiation emanating from the patient. Generally, occupational doses:

- will scale with patient doses; and
- can be lowered by:
 - reducing unnecessary patient dose; and
 - using appropriate protective equipment such as shielding devices (ICRP 2000a, Vano *et al* 1998b, 1998c).

Staff can reduce their occupational exposure by being aware of where they position themselves during a procedure. Since the patient is the source of scattered radiation, it is important that the operator and other staff remain as far away as practical from the patient. Wagner and Archer (2000) recommend that if the X-ray beam is horizontal or near horizontal, the operator should stand on the same side of the patient couch as the imaging device (image intensifier or flat panel detector). If the X-ray beam is vertical, or near vertical, the operator should keep the X-ray tube under the patient.

Protracted exposures may also cause damage to the eyes (Vano *et al* 1998a, Haskal and Worgul 2004). Practitioners who perform interventional radiology procedures should therefore wear lead glass spectacles. Thyroid shields are also recommended. Ideally, there should also be ceiling

suspended lead glass viewing windows at the patient couch since they offer superior radiation protection.

Wagner and Archer (2000) also report significant injuries to the hands of practitioners performing interventional procedures. All persons need to avoid placing their hands in the unattenuated primary X-ray beam. The use of forceps may aid in reducing the frequency of such occurrences and as a final resort, the practitioner should consider wearing leaded gloves although issues of dexterity and sterility may take precedence.

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10. Site Requirements

10.1 RADIATION SHIELDING

The Responsible Person needs to give careful consideration to the:

- siting of X-ray units; and
- provision of structural shielding.

These considerations are particularly important when an X-ray unit is:

- operated in close proximity to occupied areas; or
- used in a confined space.

Shielding requirements need to be individually tailored to suit the practice requirements based on the intended patient workload and the type of examinations to be undertaken. Further assessments should be undertaken when:

- the intended use of a room changes;
- X-ray equipment is upgraded; or
- surrounding room occupancy is altered.

Accordingly, the Responsible Person should seek the advice of a qualified expert or other individual experienced in performing such calculations. The literature (NCRP 2004, BIR 2000) or the relevant regulatory authorities listed in Annex D might also provide advice on structural shielding issues.

As a general requirement, all shielded barriers should be designed according to the requirements of the relevant regulatory authority. Despite that, barriers should:

- be at least two metres high; and
- have all penetrations and joints arranged so that they are equally as effective in shielding radiation.

Any viewing windows in walls or doors need to have at least the same lead equivalence as the minimum shielding specifications for the shielded barrier in which they are located. Due consideration should be given to the provision of floor and or ceiling shielding when rooms immediately below and above the X-ray installation respectively are occupied.

Where estimating shielding for CT installations, the Responsible Person should insist that the equipment suppliers provide radiation scatter contour maps around the scanner as part of the documentation accompanying the equipment.



Section 3.1.18 of the Code requires that the Responsible Person provide visible warning signs or other devices at any general access point to a room used for diagnostic or interventional radiology. Warning signs using the trefoil symbol should conform to the specifications noted in the Australian Standard (AS 1994). The accompanying figure shows an example warning sign.

For fluoroscopic or CT equipment, a warning light that is illuminated whenever the X-rays are being produced should be provided.

Interventional radiology equipment should be equipped with ceiling suspended lead glass viewing windows at the patient couch.

11. Training

11.1 RADIATION HEALTH PROFESSIONALS

Clause 3.1.16 of the Code requires that operators and other practitioners have appropriate training to:

- perform; or
- direct exposures,

using ionizing radiation.

Radiation health professionals (i.e. radiologists and radiographers) will have such knowledge from the courses that lead to their professional qualification. The Responsible Person should however provide additional training specific to the equipment used at the institution. In some instances, such as CT and interventional equipment, the equipment supplier's representative can provide training during installation but the responsibility for ongoing training lies with the Responsible Person. The Responsible Person should also provide on-going refresher training on other radiation safety matters, for example an annual update from the RSO.

11.2 OTHER PROFESSIONAL GROUPS

Other professional groups (specialists, nurses etc), who perform or direct exposures using ionizing radiation, should also have appropriate training. A suitably qualified person (e.g. a radiology medical physicist or other person with relevant experience in radiation safety) should deliver training which includes the following 'core of knowledge':

- the responsibility of the individual in maintaining a safe workplace;
- risk-benefit analysis of using ionizing radiations;
- the importance of good clinical examination prior to exposure;
- the importance of previous examination results;
- alternatives to using ionizing radiations;
- the key features of the relevant X-ray and ancillary equipment;
- film processing (where relevant);
- radiographic interpretation (where relevant);
- risk factors such as age and the tissue type being irradiated;
- measurement of radiation dose;
- knowledge of the magnitude of typical doses from different examinations;
- methods of reducing radiation doses during radiological examinations;
- minimising the occupational hazards arising from the use of radiological equipment;
- occupational dose limits; and
- the ALARA principle.

Professional bodies and relevant regulatory authorities should ensure that courses they accredit include this core of knowledge. A representative of the sponsoring organisation should issue a signed certificate to individuals undertaking and completing this training.

11.3 USERS OF INTERVENTIONAL RADIOLOGY EQUIPMENT

Additional and continuing training is necessary when operators are required to use interventional radiology equipment and should include:

- an appreciation of the magnitude of the skin doses delivered to patients during procedures they undertake on the equipment they use; and
- an awareness of their potential to cause injury.

The ICRP (ICRP 2000a) highlighted this issue in reviewing the cause of a number of the serious radiation injuries to patients. To quote:

'In many of these cases, it appears certain that the physicians performing the procedures had no awareness or appreciation that the absorbed dose to the skin was approaching or exceeding levels sufficient to cause inflammatory and cell-killing effects.'

In rare circumstances, cumulative fluoroscopy times may be useful as a surrogate for skin dose. However, this correlation will be poor when digital acquisition runs represent a significant part of the procedure (see section 4.2).

Very high radiation doses have caused skin injuries in patients:

- mainly because of poor operator technique; and
- partly because of the use of inappropriate equipment (ICRP 2000a, Koenig *et al* 2001a, Koenig *et al* 2001b, Wagner and Archer 2000).

The primer by Wagner and Archer (2000) is an excellent teaching resource in this regard.

11.4 USERS OF CT EQUIPMENT

Training forms a key component of the optimisation process in CT scanning. ICRP Publications 87 and 102 (ICRP 2000c, ICRP 2007) offer specific advice to operators on patient dose reduction strategies for:

- single slice; and
- multi-slice CT scanners.

Any training needs to relate to the site-specific CT scanner. As part of the optimisation process, training should address the impact of the scanning parameters on:

- patient dose; and
- image quality.

In particular, operators of multi-slice scanners need to receive training that highlights the impact of:

- the nominal collimated X-ray beam width;
- mAs;
- scanned volume; and
- pitch,

on patient dose and image quality (see also section 4.4 of this Safety Guide).

Operators need to be able to:

- tailor these parameters to fit the need of the specific examination on an individual patient basis;
- interpret the significance of the dose index CTDI_{vol} (or its equivalent) displayed on the operator's console of new CT scanners before irradiation; and
- understand the concept of anatomy dependent, attenuation based methods of X-ray tube current regulation that has being introduced on newer scanners (Gies *et al* 1999, Kalendar *et al* 1999, Nagel *et al* 2000).

Annex A

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Radiation Dose Estimates from Radiological Procedures

Referrers and Radiation Medical Practitioners should appreciate the magnitude of the effective doses received by patients during radiological examinations. The accompanying table provides some assistance in this respect. The tabulated numbers are guides only as the actual doses that an individual receives may vary substantially depending on the:

- patient's anatomy;
- equipment used; and
- exact type of examination undertaken.

Doses outlined in the table below only apply to adult patients. Doses are usually higher for paediatric patients (see, for example, Chapple *et al* 2002).

Approximate effective doses arising from common radiological examinations in adults*

Effective Dose Range (mSv)	Radiological Examinations
0 – 0.1	Extremities
	Skull
	Cervical spine
	Chest
0.1 – 1.0	Thoracic spine
	Lumbar spine
	Abdomen
	Pelvis
	Pelvimetry
	Mammography (2 view)
1.0 - 5.0	Intravenous pyleogram (IVP)
	Barium swallow
	Barium meal
	CT head
	CT cervical spine
	CT chest (without portal liver phase)
5.0 - 10.0	Barium enema
	Angiography – coronary
	Angiography – pulmonary
	Angioplasty –coronary (PTCA)
	CT chest (with portal liver phase)
	CT renal (KUB)
	CT abdomen/pelvis – single- phase
	CT thoracic spine
	CT lumbar spine
>10	Angiography – abdominal
	Aortography – abdominal
	Transjugular intrahepatic porto-systemic shunt (TIPS
	RF cardiac ablation
	CT chest/abdomen/pelvis
	CT abdomen/pelvis – multi-phase studies

* Based on data from Johnson *et al* 2001, Hart and Wall 2002, Heggie and Wilkinson 2000 and Heggie 2005.

When considering the irradiation of a pregnant or potentially pregnant female patient, an estimate of the potential dose to the fetus is required as the decision of whether or not to proceed with the examination may depend on the size of the fetal dose. The accompanying table provides guidance as to the likely effective dose received by the fetus as a function of gestational age from common radiological examinations. The uterus and upper large intestine are surrogates for the fetus in the 1st and 3rd trimesters, respectively. Values for the 2nd trimester will be intermediate between those for the 1st and 3rd trimesters. All doses should be treated as indicative only as individual doses can differ from the tabulated values by as much as a factor of 10, except for those examinations remote from the lower abdomen.

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Where a fetal exposure is likely to be in excess of 1 mSv, calculations using patient specific parameters need to be undertaken (Schedule B1.1 of the Code).

	Examination	1st trimester	3rd trimester
Conventiona	l Radiography*		
	Skull	< 0.01	< 0.01
	Chest	< 0.01	< 0.01
	Cervical spine	< 0.01	< 0.01
	Thoracic spine	< 0.01	< 0.01
	Lumbar spine	2	6
	Abdomen	1.5	2.5
	Pelvis	1	2
	Intravenous pyleogram (IVP)	2	10
	Extremities	< 0.01	< 0.01
	Mammography	< 0.01	< 0.01
	Barium meal	1	6
	Barium enema	7	25
CT**			
	Head	< 0.005	< 0.005
	Neck	< 0.005	< 0.01
	Chest without portal phase	0.1	0.6
	Chest with portal phase	1	7
	Chest (pulmonary embolism)	0.1	0.4
	Chest/abdomen/pelvis	12	13
	Abdomen/pelvis – single phase	12	12
	Abdomen/pelvis – multi phase	15	30
	Thoracic spine	0.2	1.0
	Lumbar spine	10	25
	Pelvimetry	-	0.2

Approximate fetal effective doses (mSv) arising from common radiological examinations of pregnant patients*

* Based on data from Sharp et al 1998 and simulations using PCXMC code

** Estimates for CT examinations are obtained using the ImPACT dose calculator and typical technique factors.

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Radiation Safety Officer

A person appointed as the Radiation Safety Officer will be thoroughly familiar with the:

- requirements of the relevant radiation safety legislation;
- provisions of the Code and this Safety Guide;
- Radiation Management Plan of the organisation;
- detailed working rules and emergency procedures adopted for use in accordance with the Code and this Safety Guide;
- radiation survey meters;
- protective equipment; and
- personal monitoring devices used to meet the requirements of the Code and this Safety Guide;

Typically, an RSO will:

- maintain and regularly review the Radiation Management Plan;
- ensure that the facility meets the requirements of the Radiation Management Plan;
- advise on actions to be taken to reduce the radiation exposure of employees or members of the public to a level that is:
 - below the radiation protection limits prescribed in RPS1; and
 - as low as reasonably achievable, social and economic factors being taken into account.
- maintain the occupational exposure records;
- provide appropriate personal radiation monitors to staff;
- maintain radiation safety records;
- ensure that radiation monitoring instruments are regularly:
 - maintained;
 - calibrated; and
 - tested;
- ensure that all staff:
 - correctly use;
 - maintain; and
 - test,

personal protective equipment;

- be responsible for the:
 - initial and continued instruction of employees in radiation hazards;
 - safe working procedures to ensure radiation protection;
 - proper use of radiation monitoring and protective equipment; and

- measures to limit radiation exposure;
- develop and implement safe work practices when using radiation sources;
- provide advice, as required, to the Radiation Medical Practitioner on the radiation safety of individual patients undergoing diagnostic or interventional procedures;
- ensure that all necessary:
 - shielding;
 - radiation safety equipment; and
 - radiation monitoring devices,

are provided;

- carry out any measurements, investigations or assessments which are deemed necessary:
 - to verify radiation safety; or
 - in the event of a radiation incident;
- investigate any defect in an:
 - area; or
 - item of equipment,

that may increase the exposure of a person to radiation;

- recommend how to correct that defect;
- review, audit and report on radiation practices to ensure their continued effectiveness;
- provide reports on radiation incidents to the:
 - Responsible Person; and
 - relevant regulatory authorities

that include:

- what happened;
- estimates of radiation exposure to individuals;
- action taken; and
- recommendations on how to prevent a recurrence;
- ensure that prescribed radiation signs are:
 - maintained in good condition; and
 - located in places in which they will be readily seen;
- perform any other tasks required to maintain a high standard of radiation safety;
- ensure that:

.

- satisfactory quality assurance (QA) programs; and
- quality control (QC) testing for radiation safe practices

are performed; and

• maintain detailed records on all the above matters.

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Annex C

Health Effects of Ionizing Radiation and Standards for **Control of Exposure**

> Annex C was removed January 2015. For information on the health effects of ionising radiation, refer to

RPS F-1 Fundamentals for Protection Against Ionising Radiation (2014)

Annex C was removed January 2015.

For information on the health effects of ionising radiation,

refer to

RPS F-1 Fundamentals for Protection Against Ionising Radiation (2014)

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Annex C was removed January 2015.

For information on the health effects of ionising radiation,

refer to

RPS F-1 Fundamentals for Protection Against Ionising Radiation (2014)

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Annex D

Regulatory Authorities

Where advice or assistance is required from the relevant radiation protection authority, it may be obtained from the following officers:

COMMONWEALTH, STATE/TERRITORY	CONTACT	
Commonwealth	Chief Executive Officer ARPANSA	
	PO Box 655	Tel: (02) 9541 8333
	Miranda NSW 1490 Email: info@arpansa.gov.au	Fax: (02) 9541 8314
New South Wales	Manager Hazardous Materials and Rad	diation Section
	Department of Environment and Climat	
	PO Box A290	Tel: (02) 9995 5000
	Sydney South NSW 1232	Fax: (02) 9995 6603
	Email: radiation@environment.nsw.gov	/.au
Queensland	Director, Radiation Health Unit	
	Department of Health 450 Gregory Terrace	Tal: (07) 2406 8000
	Fortitude Valley QLD 4006	Tel: (07) 3406 8000 Fax: (07) 3406 8030
	Email: radiation_health@health.qld.gov	
South Australia	Director, Radiation Protection Division	
	Environment Protection Authority	
	PO Box 721	Tel: (08) 8130 0700
	Kent Town SA 5071	Fax: (08) 8130 0777
	Email: radiationprotection@epa.sa.gov	<u>.au</u>
Tasmania	Senior Health Physicist	
	Health Physics Branch Department of Health and Human Serv	vices
	GPO Box 125B	Tel: (03) 6222 7256
	Hobart TAS 7001	Fax: (03) 6222 7257
	Email: health.physics@dhhs.tas.gov.au	
Victoria	Team Leader, Radiation Safety	
	Department of Human Services	
	GPO Box 4057	Tel: 1300 767 469
	Melbourne VIC 3001	Fax: 1300 769 274
Western Australia	Email: <u>radiation.safety@dhs.vic.gov.au</u> Secretary, Radiological Council	
western Australia	Locked Bag 2006 PO	Tel: (08) 9346 2260
	Nedlands WA 6009	Fax: (08) 9381 1423
	Email: radiation.health@health.wa.gov	
Australian Capital Territory	Manager Radiation Safety	
	Radiation Safety Section	
	ACT Health	
	Locked Bag 5	Tel: (02) 6207 6946
	Weston Creek ACT 2611	Fax: (02) 6207 6966
Northern Territory	Email: <u>radiation.safety@act.gov.au</u> Manager Radiation Protection	
	Radiation Protection Section	
	Department of Health and Families	
	GPO Box 40596	Tel: (08) 8922 7152
	Casuarina NT 0811	Fax: (08) 8922 7334
	Email: envirohealth@nt.gov.au	

This table was correct at the time of printing but is subject to change from time to time. For the most up-to-date list, the reader is advised to consult the ARPANSA web site (www.arpansa.gov.au).

For after hours emergencies only, the police will provide the appropriate emergency contact number.

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Annex E

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ARPANSA Radiation Protection Series Publications

ARPANSA has taken over responsibility for the administration of the former NHMRC Radiation Health Series of publications and for the codes developed under the *Environment Protection (Nuclear Codes) Act 1978.* The publications are being progressively reviewed and republished as part of the *Radiation Protection Series.* All of the Nuclear Codes have now been republished in the *Radiation Protection Series.*

All publications listed below are available in electronic format, and can be downloaded free of charge by visiting ARPANSA's website at <u>www.arpansa.gov.au/Publications/codes/index.cfm</u>.

Radiation Protection Series publications are available for purchase directly from ARPANSA. Further information can be obtained by telephoning ARPANSA on 1800 022 333 (freecall within Australia) or (03) 9433 2211.

- RPS 1 Recommendations for Limiting Exposure to Ionizing Radiation (1995) and National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002)
- RPS 2 Code of Practice for the Safe Transport of Radioactive Material (2008)
- RPS 2.1 Safety Guide for the Safe Transport of Radioactive Material (2008)
- RPS 3 Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields 3 kHz to 300 GHz (2002)
- RPS 4 Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)
- RPS 5 Code of Practice and Safety Guide for Portable Density/Moisture Gauges Containing Radioactive Sources (2004)
- **RPS 6** National Directory for Radiation Protection Edition 1.0 (2004)
- RPS 7 Recommendations for Intervention in Emergency Situations Involving Radiation Exposure (2004)
- RPS 8 Code of Practice for the Exposure of Humans to Ionizing Radiation for Medical Research Purposes (2005)
- RPS 9 Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing (2005)
- RPS 10 Code of Practice and Safety Guide for Radiation Protection in Dentistry (2005)
- **RPS 11** Code of Practice for the Security of Radioactive Sources (2007)
- RPS 12 Radiation Protection Standard for Occupational Exposure to Ultraviolet Radiation (2006)
- RPS 13 Code of Practice and Safety Guide for Safe Use of Fixed Radiation Gauges (2007)
- RPS 14 Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)
- RPS 14.1 Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (2008)

RPS 14.2 Safety Guide for Radiation Protection in Nuclear Medicine (2008)

- RPS 15 Safety Guide for Management of Naturally Occurring Radioactive Material (NORM) (2008)
- RPS 16 Safety Guide for the Predisposal Management of Radioactive Waste (2008)

Those publications from the NHMRC **Radiation Health Series** that are still current are:

- RHS 3 Code of practice for the safe use of ionizing radiation in veterinary radiology: Parts 1 and 2 (1982)
- RHS 8 Code of nursing practice for staff exposed to ionizing radiation (1984)
- RHS 9 Code of practice for protection against ionizing radiation emitted from X-ray analysis equipment (1984)
- RHS 10 Code of practice for safe use of ionizing radiation in veterinary radiology: part 3-radiotherapy (1984)
- RHS 13 Code of practice for the disposal of radioactive wastes by the user (1985)
- RHS 14 Recommendations for minimising radiological hazards to patients (1985)
- RHS 15 Code of practice for the safe use of microwave diathermy units (1985)
- RHS 16 Code of practice for the safe use of short wave (radiofrequency) diathermy units (1985)
- RHS 18 Code of practice for the safe handling of corpses containing radioactive materials (1986)
- RHS 19 Code of practice for the safe use of ionizing radiation in secondary schools (1986)
- RHS 21 Revised statement on cabinet X-ray equipment for examination of letters, packages, baggage, freight and other articles for security, quality control and other purposes (1987)
- RHS 22 Statement on enclosed X-ray equipment for special applications (1987)
- RHS 23 Code of practice for the control and safe handling of radioactive sources used for therapeutic purposes (1988)
- RHS 24 Code of practice for the design and safe operation of non-medical irradiation facilities (1988)
- RHS 25 Recommendations for ionization chamber smoke detectors for commercial and industrial fire protection systems (1988)
- RHS 28 Code of practice for the safe use of sealed radioactive sources in bore-hole logging (1989)
- RHS 30 Interim guidelines on limits of exposure to 50/60Hz electric and magnetic fields (1989)
- RHS 31 Code of practice for the safe use of industrial radiography equipment (1989)
- RHS 34 Safety guidelines for magnetic resonance diagnostic facilities (1991)
- RHS 35 Code of practice for the near-surface disposal of radioactive waste in Australia (1992)
- RHS 36 Code of practice for the safe use of lasers in schools (1995)
- RHS 38 Recommended limits on radioactive contamination on surfaces in laboratories (1995)

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- AAPM 2002. American Association of Physicists in Medicine, *Quality control in diagnostic radiology*, AAPM Report No. 74, Madison.
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Glossary

Absorbed dose

the energy absorbed per unit mass by matter from ionizing radiation which impinges upon it.

Absorbed dose, *D*, is defined by the expression:

$$D = \frac{dE}{dm}$$

where dE is the mean energy imparted by ionizing radiation to matter of mass dm.

The unit of absorbed dose is joule per kilogram (J kg $^{-1}$), with the special name gray (Gy).

Acceptance testing

a series of tests carried out after new equipment has been installed or major modifications have been made to existing equipment in order to verify compliance with contractual and manufacturer's specifications.

ALARA principle

a principle of radiation protection philosophy that requires that exposures to ionizing radiation should be kept as low as reasonably achievable, economic and social factors being taken into account. The ALARA principle is equivalent to the principle of optimisation defined by the ICRP, which states that protection from radiation exposure is optimum when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.

Approved

when applied to a plan or proposal, one which has received approval from the appropriate authority.

Authorisation

a written permission granted by the relevant regulatory authority to perform specified practices. The form of an authorisation can include a licence, registration, or accreditation.

Automatic brightness control (ABC)

a technology whereby the image on a video monitor, produced from an image intensifier or flat panel detector, is maintained at uniform brightness regardless of the anatomy being viewed.

Carer

a person who voluntarily, willingly and knowingly assists or helps in the care, support or comfort of patients undergoing a diagnostic or therapeutic medical radiation procedure.

Collimator

a fixed or adjustable device to limit the useful beam to specific dimensions.

Radiation | Computed tomography dose index

applied in the context of CT scanning, the CTDI is the integral along a line parallel to the axis of rotation (z) of the absorbed dose profile (D(z)) for a single rotation and a fixed table position divided by the nominal thickness of the X-ray beam. If the integration is restricted to a distance of 100 mm centred on the centre of the dose profile it is denoted as CTDI₁₀₀.

Weighted CTDI (CTDI_w): the CTDI obtained by measuring the CTDI₁₀₀ in cylindrical polymethylmethacrylate phantoms and weighting the results according to the following formula:

$$CTDI_{w} = \frac{1}{3}CTDI_{100,c} + \frac{2}{3}CTDI_{100,p}$$

where $CTDI_{100,c}$ refers to the CTDI on the central axis of the phantom; and $CTDI_{100,p}$ represents an average of measurements at four different locations 10 mm below the surface around the periphery of the phantom.

The CTDI_w is usually expressed in units of mGy.

Volume CTDI (CTDI_{vol}): describes the average dose over the total volume scanned and is calculated from the CTDI_w taking into account the table advance between rotations in the case of sequential scanning, or the pitch in the case of helical scanning. For sequential scanning:

$$\text{CTDI}_{\text{vol}} = (\text{N} \times \text{T} / \Delta \text{d}) \times \text{CTDI}_{\text{w}}$$

where N \times T is the total X-ray beam width for a nominal N slice scanner of detector width T (e.g. 16 \times 1.5 mm); and

 Δd represents the table advance between rotations.

For helical scanning:

$$CTDI_{vol} = CTDI_w / pitch.$$

The $CTDI_{vol}$ is usually expressed in units of mGy.

Constancy testing

a series of tests carried out; (a) to ensure that the functional performance of equipment meets established criteria; or (b) to enable the early recognition of changes in the properties of components of the equipment.

Constraint

either dose constraint in the case of exposures anticipated to be received, or risk constraint in the case of potential exposures (see dose constraint and risk constraint).

Conversion factor

a measure of the efficiency of an image intensifier to convert an X-ray image incident on its input phosphor to a light image on its output phosphor. The formal definition is given by:

Conversion factor = $\frac{\text{luminance of output phosphor}}{\text{absorbed dose rate at the input phosphor}}$

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Deterministic effect

an effect, such as partial loss of function of an organ or tissue, caused by radiation and manifest only above some threshold of dose, the severity of the effect depending upon the dose received.

Detriment

a measure, or measures, of harm caused by exposure to radiation and usually taken to mean health detriment; it has no single definition, but can be taken to be an attribute or a collection of attributes which measure harm, such as attributable probability of death and reduction of life expectancy.

Diagnostic reference level (DRL) for medical exposure

dose levels for medical exposures in medical radiodiagnostic practices, or levels of activity in the case of radiopharmaceuticals, applied to groups of standard-sized patients or standard phantoms for common types of diagnostic examination and broadly defined types of equipment. These levels are expected not to be consistently exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. DRLs will be set by relevant professional bodies and published by ARPANSA or the relevant regulatory authority from time to time.

Dose

a generic term which may mean absorbed dose, equivalent dose or effective dose depending on context.

Dose-area product (DAP)

the product of the absorbed dose in air and the area of the X-ray beam at a point in a plane perpendicular to the central axis of the X-ray beam. It does not include contributions from backscatter but is a useful dosimetric quantity for fluoroscopic and other complicated radiological examinations. The DAP may be expressed in units of Gy.cm².

Dose-length product (DLP)

a dosimetric quantity applicable to a complete CT examination that may be estimated approximately from the volume CTDI through the equation:

$$DLP = \sum_{i} CTDI_{vol} \times L$$

where L is the length of the scanned volume, corrected for any overscanning; and

the summation is over all scan sequences forming part of the examination.

The DLP is usually expressed in units of mGy.cm.

Radiation | Dose constraint

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a prospective restriction on anticipated dose, primarily intended to be used to discard undesirable options in an optimisation calculation.

In occupational exposure, a dose constraint may be used to restrict the options considered in the design of the working environment for a particular category of employee.

In medical exposure, a dose constraint for volunteers in medical research may be used to restrict the options considered in the design of an experimental protocol.

In public exposure⁴, a dose constraint may be used to restrict the exposure of the critical group⁵ from a particular source of radiation.

Effective dose

a measure of dose which takes into account both the type of radiation involved and the radiological sensitivities of the organs and tissues irradiated.

Effective dose, *E*, is the sum of weighted equivalent doses in all organs and tissues of the body. It is given by the expression:

$$E = \sum_{T} W_{T} H_{T}$$

where H_T is the equivalent dose in organ or tissue *T* and w_T is the tissue weighting factor for that organ or tissue.

The unit of effective dose is J kg⁻¹, with the special name sievert (Sv).

Employee

a person who works for an employer within an operation.

Employer

an operator who or which engages people to work within an operation; the term employer includes a self-employed person.

Entrance surface dose (ESD)

the value of the absorbed dose in air, including backscatter, at the intersection of the central axis of the X-ray beam with the entrance surface of the patient. It is a useful dosimetric quantity for simple radiological examinations and is usually expressed in units of mGy.

Exposure

the circumstance of being exposed to radiation.

⁴ Public exposure is the exposure of a person, or persons, to radiation that is neither occupational nor medical exposure.

⁵ A group of members of the public comprising individuals who are relatively homogeneous with regard to age, diet and those behavioural characteristics that affect the doses received and who receive the highest radiation doses from a particular practice.

Exposure factors

the X-ray tube potential in kilovolts (peak) (kV peak) and milliamperes (mA) and the exposure time in seconds (s), or the product of the tube current and exposure time in milliampere seconds (mAs).

Filtration

the modification of the spectral distribution of an X-ray beam as it passes through matter, due to the preferential attenuation of particular photon energies in the radiation beam.

Added filtration: quantity indicating the filtration effected by added filters in the useful beam, but excluding inherent filtration.

Inherent filtration: the filtration effected by the irremovable materials of the X-ray tube assembly through which the radiation beam passes before emerging from the X-ray tube assembly.

Total filtration: the total of inherent filtration and added filtration between the radiation source and the patient or a defined plane.

Flat panel detector

a transducer that employs solid state technology to convert an X-ray image to an electronic image. The image may be viewed using a video chain, as in fluoroscopy, or on a computer monitor when used as an alternative to film-screen technology.

Image intensifier

a transducer that employs vacuum tube technology to convert an X-ray image to a light image suitable for viewing by a video chain.

Interventional radiology

procedures comprising guided therapeutic and diagnostic interventions, by percutaneous or other access, usually performed under local anaesthesia or sedation, with fluoroscopic or computed tomographic imaging used to localise, in conjunction with a surgical procedure, the lesion/treatment site, monitor the surgical procedure, or control and document the therapy or diagnosis.

Ionizing radiation

electromagnetic or particulate radiation capable of producing ions directly or indirectly, but does not include electromagnetic radiation of a wavelength greater than 100 nanometres.

Justification

the notion that human activities which lead to exposure to radiation should be justified, before they are permitted to take place, by showing that they are likely to do more good than harm.

Lead equivalence Radiation

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at a specified kilovoltage (kV peak) and x-ray beam quality, the thickness of lead effecting the same attenuation as the material under consideration.

Medical exposure

exposure of a person to radiation received as a patient undergoing medical diagnosis or therapy, or as a volunteer in medical research, or non-occupational exposure received as a consequence of assisting an exposed patient.

Occupational exposure

exposure of a person to radiation which occurs in the course of that person's work and which is not excluded exposure⁶.

Operator

any natural person who is authorised by the relevant regulatory authority to administer radiation to a patient for radiology, nuclear medicine or radiotherapy.

Optimisation

The process of maximising the net benefit arising from human activities which lead to exposure to radiation.

Pitch

Applied in the context of helical CT scanning, the pitch may be defined as the ratio of the patient couch advance per rotation to the total width of the collimated X-ray beam at the patient isocentre.

Practice

a type of human activity; in a radiological context, a human activity which may result in exposure to ionizing radiation and to which a system of radiation protection applies.

Qualified expert

a person who:

- (a) is qualified in the application of the physics of therapeutic or diagnostic uses of ionizing radiation; and
- (b) has been recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to the person's area of expertise⁷.

Excluded exposure is, in the context of occupational exposure, the component of exposure which arises from natural background radiation, provided that any relevant action level, or levels, for the workplace are not exceeded and that the appropriate authority does not prohibit its exclusion.

Competency requirements for a qualified expert will be listed in future editions of the National Directory for Radiation Protection.

Radiation incident

any unintended or ill-advised event when using ionizing radiation apparatus, specified types of non-ionizing radiation apparatus or radioactive substances, which results in, or has the potential to result in, an exposure to radiation to any person or the environment, outside the range of that normally expected for a particular practice, including events resulting from operator error, equipment failure, or the failure of management systems that warranted investigation.

Radiology medical physicist

for the purpose of this Safety Guide, is a person who is qualified to perform the necessary dosimetric calculations, measurements and monitoring. A suitable person will:

- (a) be on the Register of Radiology Medical Physicists held by the Australasian College of Physical Scientists and Engineers in Medicine; or
- (b) have an equivalent level of training, skills, knowledge and expertise to a person listed on the Australasian College of Physical Scientists and Engineers in Medicine Register of Radiology Medical Physicists as determined by the relevant regulatory authority.

Radiation Medical Practitioner

the practitioner authorised by the relevant regulatory authority and responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation. In nuclear medicine, this person will normally be a nuclear medicine specialist, in radiation oncology, this person will normally be a radiation oncologist and in diagnostic or interventional radiology, this person will usually be a radiologist, but might also be, for example, a cardiologist or, for limited procedures, a general practitioner.

Referrer

a registered medical practitioner, dentist or other health professional who is entitled to refer individuals to the Radiation Medical Practitioner who will be responsible for the overall conduct of the procedure involving the exposure of the patient to ionizing radiation.

Relevant regulatory authority

the radiation protection authority or authorities designated, or otherwise recognised, for regulatory purposes in connection with protection and safety relating to medical applications of ionizing radiation.

Responsible person

in relation to any radioactive source, radiation-producing equipment, prescribed radiation facility or premises on which radioactive sources are stored or used means the legal person⁸:

(a) having overall management responsibility including responsibility for the security and maintenance of the source, radiation-producing equipment, facility or premises;

⁸ A legal person can be a natural person, a body corporate, a partnership or any other entity recognised as a 'legal person' by the legislation in the jurisdiction.

- (b) having overall control over who may use the source, radiation-producing equipment, facility or premises; and
- (c) in whose name the source, radiation-producing equipment, facility or premises would be registered if this is required.

Stochastic effect

an effect known to occur sometimes as a consequence of exposure to radiation, but which may or may not be expressed in a particular exposed person, the likelihood of the effect occurring being a function of the dose received.

X-ray

ionizing electromagnetic radiation emitted during the transition of an atomic electron to a lower energy state or during the rapid deceleration of a charged particle.

X-ray tube current

the electric current flowing through an X-ray tube during an exposure expressed in milliamperes (mA).

Contributors to Drafting and Review

WORKING GROUP

Associate Professor John Heggie	Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) (Convenor of working group)
Dr Grant Bigg-Wither	Royal Australian and New Zealand College of Radiologists (RANZCR)
Prof Scott Bowman	Australian Institute of Radiography (AIR)
Mr Peter Collins	Australian and New Zealand Society of Nuclear Medicine (ANZSNM)
Mr Paul Einsiedel	Department of Human Services, Victoria
Mr Bruce Harvey	Australian Institute of Radiography (AIR)
Dr Mark Horrigan	Cardiac Society of Australia and New Zealand
Dr Alex Pitman	Royal Australian and New Zealand College of Radiologists (RANZCR)
ARPANSA Secretariat	

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